

K240604 MTONE EVO (MTONE EVO)Sep 20, 2024
200 days to decisionK240604 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 4, 2024
Decision date	Sep 20, 2024
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	M&T S.R.L.
Location	Rimini, IT
Contact	Fiorenzo Rossi
510(k) history	4 submissions · 4 cleared · 2017-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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